

A. Inventive Steps of Present Invention compared to prior art cited by Examiner.

One of the critical inventive steps of the present invention is the introduction of significantly expanded functionality to a device that takes the physical form of a stethoscope. As stated in the following two quotes from the specification of the present invention:

"The present invention relates to a medical communications, information and measurement device with multiple functions built into the same unit, to produce a portable device. The preferred embodiment is in the form of a stethoscope-like device with expanded, general-purpose medical measurement, information and communications functions, beyond the basic auscultation functions."

"... the transition from a mechanical to an electronic stethoscope introduces the potential to expand the functionality of the stethoscope, using it as a more general-purpose electronic platform for other functions that are useful to the medical worker. The form factor of the stethoscope allows it to be worn comfortably around the neck or shoulders, and the audio input and output functions can be used for other applications beyond auscultation. The fact that it is carried around so extensively in the medical setting makes it an ideal platform for many additional functions of an electronic nature."

The present invention therefore provides for a device that looks, feels, and is worn like a stethoscope, but has functions and

features that go far beyond merely a device for listening to body sounds. This is in contrast to the prior art, as discussed below.

Historically, the stethoscope has been viewed as a single-function device, intended for listening to body sounds. This is understandable in the context of mechanical or acoustic stethoscopes, which comprise a pneumatic audio device that is little more than a pair of hollow tubes. Such a structure has essentially no other purpose than auscultation (listening to body sounds).

The transition to electronic stethoscopes is shown in the prior art to follow two approaches, and prior art cited by Examiner reflects the two approaches:

Electronic Equivalent - The first approach, characterized by Grasfield (5,825,895), as cited by Examiner, introduces electronics into the processing of body sounds, to create an electronic version of the conventional mechanical stethoscope. Such devices maintain the essential character of the stethoscope as a single-use device intended for listening to body sounds. Improvements center around the versatility of electronic filtering, recording body sounds, transmitting body sounds to remote systems, and other expansions of the basic auscultation functionality. Myriad auscultation-related features are shown in the prior art. Nevertheless, the stethoscope, as cited, remains purely a body sound processing device, with similar look, form, and function to the conventional stethoscope.

Handheld Pocket Calculator Device - The second approach, characterized by Villa-Real (4,320,767), as cited by Examiner, disclose some stethoscope-like functionality in a handheld

calculator form that bears no physical resemblance to a stethoscope. It cannot be worn like a stethoscope, given its handheld form factor. In Villa-Real, the calculator provides the blood pressure function of a stethoscope and blood pressure cuff combination, and Villa-Real introduces some limited extension to functionality by offering pulse rate measurement as well. Body sounds can be heard while making these measurements, via a loudspeaker or external headphones, and Villa-Real teaches against the use of conventional earphones of the physical form associated with stethoscopes. Villa-Real provides for some limited modular extensions to functions beyond the limitations of Grasfield.

The Grasfield paradigm is thus an electronic stethoscope with auscultation functionality, mimicking a mechanical stethoscope. The Villa-Real paradigm is the handheld or pocket calculator device that is mechanically entirely dissimilar to a stethoscope but includes some of its functionality, as well as some extensible functionality. These two inventions anticipate, nor do they suggest, the present invention, as discussed in more detail below.

The present invention makes significant inventive steps beyond the prior art by uniquely combining the physical form of a stethoscope (in look, feel, mechanical structure, and manner of being worn around the neck or shoulders) with expanded functionality (of a more general-purpose computer or medical measurement apparatus), such expanded functionality going far beyond that suggested or disclosed by Villa-Real. The inventive steps, which make the combination advantageous and non-obvious, are as follows:

- a. While the conventional stethoscope, comprising only hollow tubes, is only suitable for a single function, listening, the electronic stethoscope comprises functional elements (electrical power source, CPU, memory, computational power, communications links) which are general-purpose building blocks. Applicant recognizes in the present invention that use of such electronic elements for auscultation should not, and does not, eliminate their use for more general-purpose functions, or restrict their use to auscultation.
- b. Instead of narrowly emulating the conventional stethoscope, by configuring the new electronic elements exclusively for body sound detection and processing, the general-purpose nature of the new elements should be exploited, using the same elements to invent a device with capability beyond auscultation. There is unrecognized potential for other uses and combinations.
- c. Since the new elements of the stethoscope are already required for auscultation, there is little or no incremental cost in expanding the functionality of the electronic stethoscope, resulting in an invention that provides economy and functionality at reduced cost.
- d. Regarding mechanical form factor, the prior art approach is to configure electronic functional elements in handheld or pocket-sized configurations, these being considered most user-friendly, easy to carry and operate. It is also far easier to package electronics in a calculator-like device, since it provides large flat areas for printed circuit boards. However, the stethoscope-like mechanical form is more familiar to the medical worker, especially if stethoscope functions are to be incorporated in the invention. Therefore, instead of configuring stethoscope

functions into the form of a handheld or pocket device, the reverse invention has superior ergonomic and familiarity advantages in the medical work environment.

- e. Therefore, use reverse logic, and configure expanded and more general functional capability into a stethoscope-type physical form, and provide the medical worker with a form that is familiar, economical, fits into the traditions of the medical work environment, provides stethoscope functions in their most familiar form, and add new functionality in a very novel form, but nevertheless consistent with the stethoscope form and use.
- f. While the mechanical form of a stethoscope is most convenient for wearing and use in the medical setting, the stethoscope form does not have the user interface of a handheld device, with keypads and displays. Therefore, the invention must solve the problem of user interfaces in a device that is worn and used like a stethoscope, necessitating the invention of novel user-interface elements and methods.
- g. Once the device has been extended functionally, with user interface means adapted to the form factor of the new invention, and computational and communications capability that is now more flexible than mere auscultation functions, invent functions and combinations of functions that are useful to medical workers in a portable form, at the point of care, such as at the bedside or in the medical examination room.

As demonstrated by the multiple inventive steps, the transition from the devices as invented by Grasfield and Villa-Real to the present invention, the new invention is non-obvious, and provides

synergistic benefits that accrue from the combination of functions.

It is thus to be emphasized, that one aspect of the present invention that is unique and unsuggested by the prior art, is the use of the form factor and manner of wearing and using a device that has the physical characteristics of a stethoscope, but which exploits the synergies of embedding electronics in such a form for auscultation, and then extending the use, applications and functions of the device far beyond those of a fixed-function auscultation device. Such a combination and extension provides utility, portability, availability at the point of care, and functionality that has significant novelty, and unexpected practical utility over the conventional teachings of embedding new devices in handheld or computer-like devices.

Considering the question of mechanical form and the cited prior art in more specific detail, Grasfield and Villa-Real are now considered in further detail.

Grasfield discloses an electronic stethoscope which is entirely unitary in its purpose. While it shares the physical structure of a conventional stethoscope, as in the present invention, the functionality and elements are focused entirely on the auscultation function. Grasfield Figures 12-15 show all the electronic functional elements in detail. The circuitry comprises essentially an analog signal path for processing body sound signals. These circuit elements are analog or switched-capacitor filters whose only programmability lies in being able to change filter bandwidth. Grasfield discloses the specific semiconductor devices (col. 19 lines 42-60, col. 20 lines 1-20). Those skilled in the art recognize these components as analog in nature. The

programmability of switched-capacitor filters is limited to changing filter cutoff frequencies. The microcontroller device has fixed one-time programmable memory, and software code which is entirely dedicated to controlling the audio signal path for processing body sounds signals, and there is no means to update the software. Grasfield makes no provision in the electronics for adding new functionality, or changing the functionality beyond auscultation. Grasfield further makes no suggestion that there is any desirability in an electronics topology that would provide for expanded functionality beyond auscultation. Grasfield therefore discloses an invention entirely dedicated to the fixed function of auscultation, with no means to change anything beyond basic filtering parameters. Grasfield does not suggest anything that would include the functions or form suggested by Villa-Real.

Villa-Real discloses a hand-held device with the internal architecture of a more general-purpose computational device (CPU, memory, display), such as might be found in a handheld calculator, with body sound sensor means to detect body sounds. However, Villa-Real teaches that the most desirable form of such an invention is in the physical form of a handheld device. Villa-Real therefore teaches against the present invention, which is in the form of a stethoscope. Villa-Real teaches not one, but eight different handheld configurations (Villa-Real figs 1-9), placing enormous emphasis on the advantages of placing an auscultation sensor in a handheld or pocket device rather than a stethoscope. Villa-Real teaches that external headphones or a built-in loudspeaker be used, in preference to built-in stethoscope-like earphones.

In short, Villa-Real teaches against the stethoscope-like physical structure of the present invention, and Grasfield

teaches a single-purpose electronic stethoscope, with no suggestion to provide expanded functionality. There is also no suggestion in Grasfield that the functions provided by Villa-Real be incorporated into an electronic stethoscope. At a general level, therefore, the present invention of a stethoscope-like device with expanded functionality is unsuggested by the prior art taken individually, or in view of the other. The next section examines the detailed disclosures of the prior art, compared to the present invention, to further dissect the prior art as it pertains to the present invention.

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B. Detailed Examination of Prior Art and Consideration of
Examiner's Claims Rejections

While the present invention is unique regarding the combination of physical embodiment of expanded functionality as presented above, it is also unique in the specific details, which are also inventive and original compared to the prior art, as discussed below, in examination of the prior art cited by Examiner, and the claim rejections.

Presented below is Applicant's response to Examiner's rejections based on the cited prior art. New claims are submitted in the following section. Applicant's response to Examiner's rejections of previous claims are in some cases pertinent to the redrafted claims, since the response below provides guidance as to the differences between the invention and the prior art, and such differences are in some cases incorporated into the new claims.

Regarding Claim 1, Applicant agrees with Examiner that the elements recited in Claim 1 as written appear similar to elements recited in Grasfield, however some detailed and important differences are to be noted.

The present invention discloses different secondary audio sources from the prior art. In particular, the present invention discloses a built-in microphone (130 Fig. 1, 130-130a Fig. 3) for voice recording (as distinct from a microphone for sensing body sounds). Grasfield's secondary audio sources are a jack connector transceiver interface (114, Fig 2) for connecting to external secondary audio sources, and a waveform memory (310, Fig. 15). Villa-Real provides for an internal synthesized speech generator (135, Fig. 19). Neither Grasfield nor Villa-Real disclose a

built-in microphone positioned for the sole purpose of detecting voice, rather than body sounds.

Regarding Claim 17, Applicant agrees that Villa-Real discloses an electronic stethoscope sensor physically attached to a handheld device containing audio driver means for processing and producing stethoscope sounds. However, Villa-Real's handheld device is not a "handheld computer" as generally understood by those with ordinary skill in the art, who would consider general-purpose devices such as PDAs (Palm Pilot or Pocket PCs) to be handheld computers. Villa-Real discloses a custom, function-specific handheld calculator device with custom-programmed computational capability, as compared to the general-purpose nature of a handheld computer, as disclosed in the present invention.

Regarding Claim 4, Villa-Real discloses a synthesized speech generator for converting data to speech output. However, as detailed above, Villa-Real teaches away from the present invention regarding the physical embodiment of the present invention as a stethoscope. Villa-Real teaches multiple pocket-sized hand-held embodiments. There is also no suggestion in Grasfield that Villa-Real's speech synthesizer be incorporated into Grasfield's electronic stethoscope. Therefore the combination of speech synthesis into a stethoscope-like physical embodiment is an unsuggested combination.

Claim 4 has been re-drafted to narrow the claim to a stethoscope-like physical embodiment, in order to clarify the distinction between the prior art and the present invention.

Regarding Claim 5, Applicant finds no reference to heart rate measurement in the quoted reference (Grasfield Col. 2, lines 34-35).

Regarding Claims 12-13, Villa-Real does teach a display means, however the present invention discloses a "virtual display means" which produces a "virtual image when viewed close to the eye". This is a different display device from the LED/LCD numerical displays disclosed by Villa-Real, and is specific to an embodiment that provides high-density information in a device that can take the physical form of a stethoscope.

Regarding Claim 14, Applicant finds no disclosure in the provided reference (Villa-Real col. 15, lines 22-34) for "storing software programs downloaded via digital communications means" as claimed in the present invention. Applicant finds no disclosure of the claimed invention, anywhere in either Villa-Real or Grasfield.

Updating programs in a stethoscope device is a unique feature of the present invention, and is counter-intuitive for medical devices, wherein regulatory requirements put stringent controls on the practice of updating software in a device such as a stethoscope. The capability to download software to a device in this manner requires multiple new inventive steps including choice of the type of memory, communications means to transmit digital content, the method of connection between the communications means and the CPU and memory. Further, there is a critical difference between transferring data, or sounds, between a stethoscope or other medical measurement device, and updating its software, since data and program software is entirely different. The present invention is unique and original in providing a method for increasing the functionality and flexibility of a stethoscope-like device by being able to change

the software in a device that can be worn around the neck or shoulders and carried in the medical work environment in this manner, and providing for a communications means that has such high flexibility that any program, physiological data, or any other type of digital content can be exchanged with the device. The prior art is far more restrictive, with no suggestion that such advanced communication has any benefit or application to a stethoscope-like device.

Regarding Claim 15, Applicant find no disclosure in the provided reference (Villa-Real col. 11, line 55 col. 12 line 6) to a handheld digital computer. Elsewhere, Villa-Real discloses a custom handheld electronic calculator and measurement device, which would typically not be considered a handheld digital computer, as is customarily understood by those with ordinary skill in the art. A handheld digital computer is a general-purpose device such as a Palm Pilot or Pocket PC.

Regarding Claim 16, Grasfield discloses a wired or wireless communications means. However, the block diagrams in Grasfield Figures 12-15 clearly show that the communications means, transceiver 120, is operatively connected to the audio signal pathway, and therefore only audio signals can be transferred via the communications means as disclosed by Grasfield. Further, Grasfield does not disclose a "digital" communications means i.e. a communications means that can transfer digital data, since it is connected to an audio circuit. Given Grasfield's circuit implementation, as evidenced by Figures 12-15 and components listed (col. 19 lines 45-60, col. 20 lines 1-20) transceiver 120 provides only analog audio signal communications rather than transmission of digital content. Grasfield further teaches that transceiver 120 is intended for transmission of auscultation

sounds (col. 12 lines 50-67, col. 13 lines 1-22). There is also no mechanism in Grasfield to actually "access" remote medical information i.e. send requests, control signals, or messages to a remote medical information storage and retrieval means. Grasfield therefore provides only very limited communications functionality whereby analog audio signals can be communicated. This is a very narrow communications capability compared to the present invention, with different function, purpose, and digital content and control capability.

In considering the details of Grasfield and Villa-Real, the prior art does not disclose the detailed aspects of the present invention as claimed. In considering the overall invention, Villa-Real teaches a hand-held approach to the medical device, and there is no suggestion in Grasfield to combine the functions of Villa-Real with Grasfield.

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C. Revised Claims

Applicant submits new claims containing same subject matter as previous claims, with clarification of definitions of unique aspects and elements of the invention - specifically the particular embodiment of the device as a wearable stethoscope, combined with expanded functional elements. Such claims are drafted to clarify and define the inventive elements in light of Examiner's rejections and the prior art. No new subject matter is claimed, however the elements of the invention are slightly rearranged to increase logical consistency among claims.\

New Claims

Claims 19: An electronic stethoscope with expanded program execution and communications capability, comprising:

A portable housing in the physical form of a stethoscope that is wearable around the neck or shoulders of an operator, to house further elements of the invention comprising

Central processing unit,

Digital memory means,

Software programs stored in digital memory means and executable by said central processing unit,

Digital communications means,

Wherein software programs can be downloaded via digital communications means, stored in digital memory, and executed by central processing unit.

20. The electronic stethoscope as in Claim 19 wherein digital memory means is non-volatile memory selected from the group Flash memory, EEPROM, battery-backed RAM.

21. The electronic stethoscope as in Claim 19 wherein digital memory means is magnetic media with software programs storage.

22. The electronic stethoscope as in Claim 19 wherein digital memory means is physically removable from electronic stethoscope housing.

23. The electronic stethoscope as in Claim 19 wherein digital communications means is a wired cable.

24. The electronic stethoscope as in Claim 19 wherein digital communications means is an infrared optical communications link.

25. The electronic stethoscope as in Claim 19 wherein digital communications means is a wireless communications link.

26. The electronic stethoscope as in Claim 19 wherein digital communications means is a wireless communications means physically removable from said electronic stethoscope housing.

27. The electronic stethoscope as in Claim 19 wherein digital communications means uses an 802.11 communications protocol.

28. The electronic stethoscope as in Claim 19 wherein digital communications means uses an Internet protocol selected from the group TCP/IP, FTP, PPP communications protocols.

29. The electronic stethoscope as in Claim 19 wherein one or more software programs are medical information software programs

selected from the group drug dosage database access software, drug interaction database access software, medical research database access software.

30. The electronic stethoscope as in Claim 29 further comprising a barcode reader operatively connected to central processing unit such that database reading and writing can be effected by barcode scanner input.

31. The electronic stethoscope as in Claim 19 wherein software includes algorithms for the processing of auscultation sounds.

Claim 32: An electronic stethoscope with expanded physiological measurement capability, comprising:

A portable housing in the physical form of a stethoscope that is wearable around the neck or shoulders of an operator, to house further elements of the invention comprising;

Central processing unit,

Battery power supply,

First physiological measurement means for detecting and reproducing body sounds,

Additional physiological measurement means selected from one or more of the group blood oxygen measurement means, blood glucose measurement means.

Wherein central processing unit and battery power supply provide control and electrical power respectively to all of said physiological measurement means, and housing provides a unified portable platform for carrying all said elements.

33. The electronic stethoscope as in claim 32, wherein additional physiological measurement means are in modular form that are physically removable from said portable housing.

Claim 34: An electronic stethoscope with expanded display capability comprising:

Auscultation sensor and electronics to sense body sounds,
Headphones for reproducing body sounds,
A miniature virtual display device which provides information display by placing the eye close to the display screen and viewing a virtual image,
Digital communications means,
User input and control means,
wherein auscultation sensor, headphones, virtual display, user input and control means, and digital communications means are housed in the physical form of a stethoscope that can be worn by an operator around the neck or on the shoulders.

Claim 35: An electronic stethoscope with expanded patient information acquisition capability, comprising:

A portable housing in the physical form of a stethoscope that is wearable around the neck or shoulders of an operator, to house further elements of the invention comprising;

Central processing unit,
Battery power supply,
Physiological measurement means for detecting and reproducing body sounds,
Additional patient information acquisition means selected from one or more of the group barcode scanner for optical scanning of barcode labels for patient records, video input means to record still or moving images of a patient,

Wherein central processing unit and battery power supply provide control and electrical power respectively to all of said physiological and patient information acquisition elements, and

said housing provides a unified portable platform for housing, carrying and operating said elements.

Claim 36: An electronic stethoscope with expanded audio capability, comprising:

A portable housing in the physical form of a stethoscope that is wearable around the neck or shoulders of an operator, to house further elements of the invention comprising;

Central processing unit,
Battery power supply,
First audio input means for detecting body sounds,
Second audio input means for detecting voice sounds,
Digital memory means for recording said body sounds and voice sounds,

Headphones for audio reproduction integrated into portable housing,

Wherein central processing unit, battery power supply, and digital memory means provide control, electrical power, and storage capability, respectively, to both first and second audio input means, said headphones provide audio output for both first and second input means, and said housing provides a unified portable platform for housing and carrying said elements.

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Favorable reconsideration of the application and claims is now respectfully solicited.

If the Examiner has any questions, he is invited to contact the undersigned at (818)710-2788.

Please acknowledge receipt hereof by stamping and returning the enclosed return postcard.

Respectfully submitted,



Colin P. Abrahams (Reg. No. 32,393)
Attorney for the Applicant
5850 Canoga Avenue, Suite 400
Woodland Hills, California 91367
Tel: (818)710-2788; Fax: (818)710-2798

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Colin P. Abrahams